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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/619,198	07/19/2000	Hai Yan	MBHB00-422	2259

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02/19/2004

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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 02/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/619,198

Applicant(s)

YAN ET AL.

Examiner

Robert C. Hayes, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-9, 12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-9, 12 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed 11/21/03 has been entered.
2. The rejection of claims 6-9 & 12-13 under 35 U.S.C. 112, second paragraph, as being indefinite for the recitation of “a non-VGF gene fused to the amino acid sequence of SEQ ID NO: 7” is withdrawn due to the amendment of the claims.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Applicants' arguments filed 11/21/03 have been fully considered but they are not deemed to be persuasive.
5. The amendment filed 4/24/03 stands objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure remains as follows: The new amendments to the description of Figures 2 & 3 do not have proper support within the specification based on the disclosure within the specification on pages 80-81 nor 79-80, nor based upon that disclosed in Figures 2 and 3 of provisional application no. 60/144,797; thereby, still constituting new matter.

As previously made of record, the amendment to the description of Figure 1 does appear to inherently flow from the disclosure on pages 79-80 of the specification, and Figure 1 of 60/144,797.

Applicants are still required to cancel the new matter in the reply to this Office Action, or provide evidence where proper basis for this amendment to the specification existed at the time of filing the instant application.

6. Claims 6-9 & 12-13 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons similarly made of record in Paper No: 17 (mailed 8/21/03), and as follows.

Applicants argue on pages 5-6 of the response that "one of skill in the art will recognize that a fusion polypeptide comprises two different proteins or portions of two different proteins fused together", and refers to the Oxford Dictionary of Biochemistry and Molecular Biology, which Applicants have failed to provide a copy for the Examiner's consideration, in contrast to their assertion on page 5. Second, in contrast to Applicants' assertions, the instant rejection is a new matter rejection, in which what "one of skill in the art recognizes" or not, is more appropriately an argument against enablement versus new matter. The issue is simple. Page 19, lines 11-13 of the specification states that "[t]he term "VGF fusion polypeptide" refers to a fusion of *one or more amino acids (such as a heterologous peptide or polypeptide)* ...", which clearly does not exclude the "*fusion of one or more amino acids*" present in Salton's VGF

protein to the “*amino or carboxyl-terminus of [the] VGF polypeptide*” of SEQ ID NO:7 [emphasis added]. In other words, the specification fails to exclude the larger VGF polypeptide described by Salton et al. (1991) as their invention. Nor does the specification state that “heterologous” amino acid residues must be derived from only “a *non-VGF* protein” [emphasis added], which currently prevents re-instatement of the rejection under 35 U.S.C. 102(b) as being anticipated by Salton et al. (1991), as previously held in Paper NOs: 9 & 11. Thus, Applicants' arguments are moot, because *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, 1117, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, *as of the filing date sought*, he or she was in possession of *the claimed invention* [emphasis added]”, which the specification itself does not support.

In summary, no proper antecedent basis nor conception in context with that described within the specification at the time of filing the instant application exists for the new claim limitation of “an amino acid sequence *from a non-VGF* protein covalently linked to an amino acid sequence as set forth in SEQ ID NO: 7”. Similar to that previously made of record, the different scope of fusion proteins with “a *non-VGF* protein covalently linked” are not contemplated within the instant specification, nor are any negative limitations excluding other VGF protein fusions contemplated at the time of filing the instant specification; thereby, constituting new matter.

It is noted that should claim 7 be amended to delete the recitation of “from a non-VGF protein”, and amended to a fusion protein consisting of the polypeptide of SEQ ID NO:7 fused to an IgG constant domain or fragment thereof, the rejection to claim 7 should be obviated.

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7. Claims 6-9 & 12-13 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reason made of record in Paper No: 17 (mailed 8/21/03), and as follows.

Applicants argue on page 6 of the response that “the specification provides several examples of non-VGF proteins that can be fused, directly or via a linker or adapter sequence, to SEQ ID NO: 7”. The Examiner agrees. However, the issue is that Applicants have chosen to claim the invention by now excluding that taught by Salton et al (1991). In contrast, the courts have held that negative limitations that exclude compounds do not meet the requirements of 35 U.S.C. 112 because it attempts to claim the invention by excluding what was not invented rather than what was invented. *In re Schechter*, 205 F2d 185, 98 USPQ 144 (CCPA 1953). Thus, Applicants’ arguments are not on point.

In summary, no generic “amino acid sequences from a *non-VGF* protein” are described within the instant specification, as currently claimed. Thus, one of ordinary skill in the art could not reasonably visualize what constitutes such widely-variable sequences that make up such generic “fusion polypeptides”; thereby, not meeting the written description requirements under 35 U.S.C. 112, first paragraph, for the reasons previously made of record.

It is noted that amendment of claim 7 to remove the recitation of “from a non-VGF protein”, and amendment of claim 7 to a fusion protein consisting of the polypeptide of SEQ ID NO: 7 fused to an IgG constant domain or fragment thereof, should obviate the rejection to claim 7.

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8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (571) 272-0887. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.
February 17, 2004


PATRICIA A. DUFFY
PRIMARY EXAMINER